

US EPA ARCHIVE DOCUMENT

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2011-0503]

Human Studies Review Board Advisory Committee

AGENCY: Environmental Protection Agency (EPA)

ACTION: Request for Nominations to the Human Studies Review Board (HSRB) Advisory Committee.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates with expertise in bioethics and toxicology to be considered for appointment to its Human Studies Review Board (HSRB) advisory committee. Vacancies are anticipated to be filled by September 1, 2011. Sources in addition to this Federal Register Notice may also be utilized in the solicitation of nominees.

BACKGROUND: On February 6, 2006, the Agency published a final rule for the protection of human subjects in research (71 FR 24 6138) that called for creating a new, independent human studies review board (i.e., HSRB). The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App. 2 §9 (Public Law 92-463). Each year the HSRB experiences membership terms expiring, therefore needs candidates for consideration as replacement members. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through EPA's Science

Advisor. General information concerning the HSRB, including its charter, current membership, and activities can be found on the EPA web site at <http://www.epa.gov/osa/hsrb/>.

HSRB members serve as special government employees or regular government employees. Members are appointed by the EPA Administrator for either two or three year terms with the possibility of reappointment to additional terms, with a maximum of six years of service. The HSRB usually meets four times a year and the typical workload for HSRB members is approximately 40 to 50 hours per meeting, including the time spent at the meeting. Responsibilities of HSRB members include reviewing extensive background materials prior to meetings of the Board, preparing draft responses to Agency charge questions, attending Board meetings, participating in the discussion and deliberations at these meetings, drafting assigned sections of meeting reports, and helping to finalize Board reports. EPA compensates special government employees for their time and provides reimbursement for travel and other incidental expenses associated with official government business. Currently, EPA is seeking nominations for individuals with expertise in bioethics and toxicology. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

The qualifications of nominees for membership on the HSRB will be assessed in terms of the specific expertise sought for the HSRB. Qualified nominees who agree to be considered further will be included in a "Short List." The Short List of nominees' names and biographical sketches will be posted for 14 calendar days for public comment on the HSRB website: <http://www.epa.gov/osa/hsrb/index.htm>. The public will be encouraged to provide additional information about the nominees that EPA should consider. At the completion of the comment period, EPA will select new Board members from the Short List. Candidates not selected for

HSRB membership at this time may be considered for HSRB membership as vacancies arise in the future or for service as consultants to the HSRB. The Agency estimates that the names of Short List candidates will be posted in July 2011. However, please be advised that this is an approximate time frame and the date is subject to change. If you have any questions concerning posting of Short List candidates on the HSRB web site, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

Members of the HSRB are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, each nominee will be asked to submit confidential financial information that shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The information provided is strictly confidential and will not be disclosed to the public. Before a candidate is considered further for service on the HSRB, EPA will evaluate each candidate to assess whether there is any conflict of financial interest, appearance of a lack of impartiality, or prior involvement with matters likely to be reviewed by the Board.

Nominations will be evaluated on the basis of several criteria, including: their professional background, expertise and experience that would contribute to the diversity of perspectives of the committee; interpersonal, verbal and written communication skills and other attributes that would contribute to the HSRB's collaborative process; consensus building skills; absence of any financial conflicts of interest or the appearance of a lack of impartiality, or lack of independence, or bias; and the availability to attend meetings and administrative sessions, participate in teleconferences, develop policy recommendations to the Administrator, and prepare recommendations and advice in reports.

Nominations should include a resume or C.V. providing the nominee's educational background, qualifications, leadership positions in national associations or professional societies, relevant research experience and publications along with a short (one page) biography describing how the nominee meets the above criteria and other information that may be helpful in evaluating the nomination, as well as the nominee's current business address, e-mail address, and daytime telephone number. Interested candidates may self-nominate.

To help the Agency in evaluating the effectiveness of its outreach efforts, nominees are requested to inform the Agency of how you learned of this opportunity.

Final selection of HSRB members is a discretionary function of the Agency and will be announced on the HSRB web site at <http://www.epa.gov/osa/hsrb/index.htm> as soon as selections are made.

ADDRESSES: Submit your nominations by July 6, 2011, identified by Docket ID No. EPA-HQ-ORD-2011-0503, by any of the following methods:

Internet: <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

E-mail: ORD.Docket@epa.gov.

USPS Mail: ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand or Courier Delivery: EPA Docket Center (EPA/DC), Room 3304, EPA West Building, 1301 Constitution Ave. NW, Washington, D.C. 20460, Attention Docket ID No. EPA-HQ-ORD-2011-0503. Deliveries are accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

FOR FURTHER INFORMATION CONTACT: Jim Downing, Designated Federal Official,
Office of the Science Advisor, Mail Code 8105R, U.S. Environmental Protection Agency, 1200
Pennsylvania Ave. NW, Washington, D.C. 20460; telephone number: (202) 564-2468, fax
number: (202) 564-2070, e-mail: downing.jim@epa.gov.

Dated: _____

Paul T. Anastas, Ph.D.
EPA Science Advisor